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Docket No.: 20308 US (C38435/109700CON)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :
Akira ASAKURA *et al.*

Serial No.: 09/470,667

Filed: December 22, 1999

Examiner: M. Walicka

Art Unit: 1652

For: **NOVEL ALCOHOL/ALDEHYDE DEHYDROGENASES**

New York, NY
July 30, 2001

RESPONSE TO RESTRICTION REQUIREMENT AND
REQUEST FOR A ONE-MONTH EXTENSION OF TIME

Commissioner for Patents
Washington, DC 20231

Sir:

This is in response to the Restriction Requirement mailed May 29, 2001, which set a one-month shortened statutory period for response that expired on June 29, 2001. A one-month extension of time to respond to the Restriction Requirement is hereby requested and with this petition, the Response is due July 30, 2001. 35 USC §21(b); 37 CFR §§ 1.7 and 1.8. Enclosed is a check in the amount of $110.00 to cover the fee for the extension of time. 37 CFR § 1.17 (a)(1).

It is not believed that this response occasions any additional fee, but should there be any fee, please charge the same to Deposit Account No. 02-4467. A duplicate copy of this sheet is enclosed.

On page 2 of the Office Action, the Examiner issued a nine-way restriction requirement pursuant to 35 USC § 121. The restriction divided the claims into the following allegedly distinct inventions: Group I, drawn to "an enzyme comprising a recombinant polypeptide having

alcohol and aldehyde dehydrogenase activity," containing claims 1-3 and 9; Group II, drawn to "DNA encoding said enzyme, expression vectors, recombinant host, and recombinant production of the enzyme," containing claims 4-8 and 10-16; Group III, drawn to "a process for producing aldehyde by the recombinant organism in a fermentor," containing claims 17 and 18; Group IV, drawn to "a process for producing carboxylic acid by the recombinant microorganism in a fermentor," containing claim 19; Group V, drawn to "a process for producing of [sic] aldehyde by the recombinant enzyme," containing claims 20 and 21; Group VI, drawn to "a process for producing a 2-keto-L-gulonic acid by the recombinant organism grown on L-sorbose," containing claims 23-24; Group VII, drawn to "a process for producing 2-keto-L-gulonic acid by the recombinant enzyme," containing claims 22 and 25; Group VIII, drawn to "a process for the production of L-ascorbic acid from 2-keto-L-gulonic acid using the recombinant organism," containing claims 26 and 27; and Group IX, drawn to "a process for the production of L-ascorbic acid from 2-keto-L-gulonic acid using the recombinant enzyme," containing claim 28. (Paper No. 10 at 2).

The Examiner also requires an election of species between SEQ ID NOS: 1-8. (*Id.*).

In issuing the restriction requirement, the Examiner asserted that because "[t]he several inventions above are allegedly distinct, "each from the other" that restriction for examination purposes is proper." (*Id.*).

In accordance with restriction practice, the subject matter of claims 4-8 and 10-16 (Group II), and SEQ ID NO: 1 (encoding enzyme A) is hereby elected for prosecution, with traverse.

In making the restriction requirement, the Examiner conceded that claim 1 links the inventions of Groups I and V, that claim 10 links inventions of Groups II, III, IV, VI, and VIII, and that claim 25 links the inventions of Groups VII, VIII and IX. Furthermore, the Examiner also acknowledged that upon allowance of the linking claims 1, 10, or 25, the restriction requirement as to the linked inventions shall be withdrawn. (Paper No. 10 at 4).

The Examiner asserted that the "inventions of Group I and II comprise different chemical entities, protein and DNA." The Examiner also contended that the "inventions of Group I and II

are also related as process of making and product made." Furthermore, the Examiner contended that the recombinant enzyme may be produced by chemical synthesis and is therefore distinct and requires a separate search in the patent literature and publications. (Paper 10 at 3).

As is well settled, a restriction of a product made by a process is proper if "...the examiner can **demonstrate** that the product **as claimed** can be made by another materially different process..." *See,* MPEP § 806.05(f), Rev. 1, February 2000, 800-36. The Examiner however, does not "demonstrate" that the claimed DNA can be made by a materially different process. Furthermore, the rejection does not "demonstrate," but simply concludes that, "the recombinant enzyme may be produced by chemical synthesis." (Paper 10 at 3). Accordingly, the Examiner has not demonstrated by the requisite, that Groups I and II are distinct and thus, the restriction should be withdrawn.

Groups I and II are not distinct and therefore do not require a separate search in the patent literature and publications. MPEP § 808.02, Rev. 1, February 2000, 800-36.

Additionally, the Examiner asserted that the inventions of Groups I and III, IV, VI, and VIII are unrelated because they are not disclosed as capable of use together and that they have different modes of operation, different functions, or different effects. (Paper 10 at 3).

The subject matter of Group I is related to the subject matter of Groups III, IV, VI, VIII. The inventions of Group I present more than one species used in the inventions of Groups III, IV, VI, VIII. A restriction requirement is not properly imposed if the invention presents more than one species under a claimed genus. 37 CFR § 1.141 (a) and MPEP § 806.04 (b). Therefore restriction is not proper and should be withdrawn for this additional reason.

The Examiner also asserted that the inventions of Groups I and V, VII and IX are related as product and process of use because the aldehydes, ketones and carboxylic acids may be synthesized using a catalizator distinct from said recombinant enzyme.

As is fundamental, in making a restriction requirement, the burden is on the examiner to provide an example of alternative use, but if the alternative use suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative. *See* MPEP §

806.05 (h) at 800-37. With all due respect, the process suggested in the Office Action cannot be accomplished using the enzyme and sequences of claim 1 using a catalizator. At most, the rejection makes a suggestion that aldehydes, ketones and carboxylic acids may be synthesized by any other process falling outside the scope of the claims of the subject invention. That, however, is not the proper standard for issuing a restriction requirement. For this reason also, the restriction should be withdrawn.

In making the restriction requirement, the Examiner contended that the inventions of Groups II and III-IX are related as process of making and process of using the product. The Examiner summarily concluded that the product claims are not allowable and that the restriction was proper. The Examiner further asserted that the product claims would be examined along with the elected invention. (Paper 10 at 3).

It is noted that determination of patentability of the product need not be made prior to making a requirement for restriction unless the requirement is based on a determination that the product claims are not allowable. *See*, MPEP § 806.05(i), 800-37. In the absence of any facts supporting the unpatentability of any of the present claims, restriction made prior to a determination of patentability is not proper and should be withdrawn for this reason also.

Additionally, the Examiner contended that the inventions of Groups III-IX are allegedly unrelated because the different inventions are not disclosed as capable of use together and they have different modes of production of different chemicals. (Paper 10 at 3). The Office Action provides no further evidence or reasoning to support this contention.

As is fundamental, in making a restriction requirement, the burden is on the Examiner to provide reasonable examples that recite material differences. *See,* MPEP § 806.05 (e) at 800-36. The Office Action does not provide a single specific example to support the conclusion. At, most the rejection makes a nebulous assertion that the claimed method of production may be used to practice production of different chemicals. The Office Action does not rely on the production of aldehydes, ketones, and carboxylic acids using the enzyme and sequences of Group I and Group II. In essence, what the Office Action does is to rely on any method of production using any method not using the enzymes and sequences of this invention. Thus, the standard for

issuing a restriction requirement is not properly met and should be withdrawn for this reason as well.

Finally, the Examiner restricted claims 22 and 25 to Group VII, drawn to "a process for producing 2-keto-L-gulonic acid." With all due respect, claim 22 is related to a process for producing a carboxylic acid. For this reason also restriction of claims 22 and 25 to Group VII should be withdrawn

For the reasons set forth above, withdrawal of all restriction requirements examination on the merits, and allowance of all the claims respectfully is requested. If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, Washington, DC 20231 on July 30, 2001.

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Respectfully submitted,

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